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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/832,233	04/10/2001	John A. Kink	OPHD-06331	8942
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23535 7590 06/10/2003

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,233

Applicant(s)

KINK ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Amendments filed on March 24, 2003 have been entered. Claims 1-14 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment.

Claim Rejections - 35 USC § 103

Claim 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eibl et al US Patent 5,833,984 (Eibl II) or Lai US Patent 5,747,532 in view of Muguruma et al (Prenat Neonat Med 1998;3:571-579), Eibl I (Acta Pediat 83,666-668, 1994) and further in view of Emery et al US Patent 5,420,253.

Applicant's arguments have been fully considered but are not found persuasive. Applicant argues that Eibl fails to teach anti-TNF antibodies in treating NEC. The instant claims are not directed to anti-TNF antibodies, rather, antibodies directed to TNF. There is no limitation in the claims requiring that the claimed antibodies are anti-TNF polyclonal antibodies. Therefore, Applicant's arguments are moot because it is directed to unclaimed limitations. Eibl teaches the use of IgA antibodies that limits the production of TNF. This is viewed as antibodies directed to production of TNF indirectly.

Applicant further argues that Lai does not teach methods of treating Necrotizing Enterocolitis ("NEC"). In response Examiner states that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant

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case, the rejection is based on the combined teachings of the references, not their individual teachings.

Lei provides anti-TNF antibodies that can be used in inflammatory conditions to counter the effects of proinflammatory factors including TNF. NEC is one of such diseases. Therefore, Lei provides to one of ordinary skill in the art adequate teachings to prepare anti-TNF antibodies for treatment of gastric inflammatory diseases similar to NEC.

Applicant also alleges that Lei teaches away because Lei at col 2, lines 35-44 acknowledges limited success when anti-TNF ⁱⁿ ~~is~~ ^{was} not administered at a proper time. This argument is not persuasive, because the cited passage at best advises against administering anti-TNF by itself at a later stage of the endotoxemia. This passage does not mean that anti-TNF use in endotoxemia is absolutely limited. On the contrary, Lei teaches use of anti-TNF antibody to improve survival rates when it is administered after dithiocarbamate-containing nitric acid scavenger. The instant claims do not exclude such methods; neither do they exclude the use of combination therapy in treating inflammatory diseases.

Further, Applicant's arguments greatly disregard the general knowledge available to one of skill in the art. In the instant case, the role of TNF in the development of neonate NEC has been well established in the art. Accordingly, Wolf, Eibl I and Muguruma are merely used to set forth general knowledge in the art about TNF and NEC.

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Since the role of TNF as a pro-inflammatory mediator in development of necrotic enterocolitis has been well established in the art as shown by Maguruma and Wolf, it would have been obvious to one of ordinary skill in the art at the time of invention to employ such antibodies directed to TNF for treatment of NEC, because as suggested by Muguruma and Eibl I and Wolf, the ordinary skill in the art would have had a reasonable expectation of success to alleviate pathological changes that lead to NEC when minimize TNF inflammatory effects on the colon.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahn timer Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
June 9, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200